

REMARKS

Upon entry of this amendment, claims 1, 6-10, 16-17 and 29-30 are currently pending in the present application, with claims 14, 15, 19-28 and 31-47 having been provisionally withdrawn by the Examiner as being directed to a non-elected species. Claim 1 is an independent claim drawn to an extended or controlled release product with the remaining claims under consideration depending therefrom and adding further limitations. Claims 2-5 and 11-13 have been canceled without prejudice or disclaimer to the subject matter contained therein. Claim 1 has been amended to better define the inventive subject matter. The limitations of claims 3 and 5 have been incorporated into claim 1, thus no new matter within the meaning of 35 USC 132 is added by the amendments to the claims.

Claims 1-13, 16, 17, 29 and 30 remain rejected under 35 U.S.C. §103(a) as being obvious over Krishnamurthy (U.S. Patent No. 5,508,043).

These amendments and remarks are presented in the expectation that they place this application in condition for allowance. Accordingly, entry of the remarks is respectfully requested.

**Rejection of Claims 1-13, 16, 17, 29 and 30**

**under 35 U.S.C 103(a)**

Claims 1-13, 16, 17, 29 and 30 stand rejected under 35 U.S.C. §103(a) as being obvious over Krishnamurthy (U.S. Patent No. 5,508,043) for the reasons set forth in the Office Action.

**RESPONSE**

Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

Applicant respectfully submits that the reference of record, the Krishnamurthy patent, does not teach or suggest Applicants' inventive subject matter as a whole, as recited in the claims. Further, there is no teaching or suggestion in this reference that would lead one of ordinary skill in the art to modify the reference to arrive at the subject of the amended claims with any expectation of success at the time the invention was made.

The U.S. Supreme Court in Graham v. John Deere Co., 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under § 103 by (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and (4) inquiring as to any objective evidence of

nonobviousness.

To establish a *prima facie* case of obviousness, the Examiner must establish: (1) that some suggestion or motivation to modify the references exists; (2) a reasonable expectation of success; and (3) that the prior art references teach or suggest all the claim limitations. Amgen, Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

A *prima facie* case of obviousness must also include a showing of the reasons why it would be obvious to modify the references to produce the present invention. See Ex parte Clapp, 277 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The Examiner bears the initial burden to provide some convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings. Id. at 974.

#### A. The present inventive subject matter

Independent claim 1 is drawn to an extended or controlled release encapsulated product, comprising: at least one active ingredient comprising a psychotropic; at least one erodible polymer selected from the group consisting of sodium carboxymethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose,

carboxymethyl cellulose ethyl cellulose, cellulose acetate methyl carbamate, methylcarbamate, polydiethylaminomethylstyrene, cellulose acetate, cellulose diacetate, cellulose triacetate, cellulose alkanylate, monoalkenytes, dialkenytes, trialkenytes, mono-, di- and tri-aroylates, cellulose trivalerate, cellulose trioctanoate, cellulose tripionate, cellulose diesters, cellulose disuccinate, cellulose acetate valerate, cellulose acetaldehyde, dimethylcellulose acetate, cellulose dimethylaminoacetate, semipermeable sulfonated polystyrenes, semipermeable styrenes, and mixtures thereof; and, at least one lubricating material. The product is in the form of a caplet having a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters.

The remaining claims depend from claim 1, or from a claim that depends from claim 1, and therefore necessarily contain all of the limitations found therein.

B. The prior art

The Krishnamurthy patent (U.S. Patent No. 5,508,043) discloses the controlled release of a therapeutically active agent from a controlled release matrix of sodium alginate and a calcium salt. When the composition is to be administered as a suppository, the matrix is combined with a therapeutically active agent and a

suppository base. When the composition is to be administered orally, the matrix further includes a higher aliphatic alcohol.

**C. The differences between the claimed subject matter  
and the prior art**

The differences between applicant's inventive subject matter and the cited reference is apparent from their independent and distinct disclosures and claims. Claim 1 (and the claims which depend therefrom) claim an extended or controlled release encapsulated product, comprising at least one active ingredient comprising a psychotropic, at least one erodible polymer selected from a group consisting of a number of different erodible polymers, and at least one lubricating material. The product is in the form of a caplet having a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters.

Applicants reiterate that the Krishnamurthy patent, on the other hand, is directed **only to the combination of sodium alginate and a calcium salt**. Further, the calcium salt is essential to the disclosure of Krishnamurthy in order to cross-link with the alginate when in solutions. The present claims do not recite alginates as a possible erodible polymer, much less an alginate

with a calcium salt cross-linking agent. In fact, the patent's disclosure is very limited in scope, and Applicants respectfully submit that one of ordinary skill in the art would not be led to the present claims by following the disclosure in the Krishnamurthy patent **since the Krishnamurthy patent deals only in alginates.**

Furthermore, this is also true since the Krishnamurthy patent does not disclose or discuss the size of the caplet as is claimed in the present claims. As Applicants have indicated previously, the size of the caplet aids in providing a controlled or extended release product with high levels of active ingredients and helps produce a product with uniform active ingredient content throughout. The size of the caplet also helps withstand mechanical pressure both in the processing of the caplet and in the chewing of the product in the mouth so that the active ingredients are released in the stomach of the consumer. In addition, the smaller size of the product allowed for better controlled release of the active ingredients. The smaller size results in a different erosion pattern, yet the release of the active ingredient is better controlled through the small size of the delivery medium. Thus, **the size of the caplet is an important feature of the present inventive subject matter.**

Applicants respectfully submit that the Krishnamurthy patent is silent with respect to these features and there is no motivation

or teaching within the patent to modify it in an attempt to achieve the present subject matter. As is indicated above, the patent is concerned **only** with sodium alginate **and a calcium salt** which is essential to cross-link with the alginate when exposed to solutions (col. 5, lines. 24-26). In addition, the patent **is silent as to the criticality of the size of the delivery product.** Thus, the Krishnamurthy patent is very narrow in scope, as the inventor focused only on the combination of sodium alginate and a calcium salt. There is nothing to lead one of ordinary skill in the art to modify the teachings of Krishnamurthy and expand the coverage thereof.

Since the teachings of the Krishnamurthy patent are deficient in disclosing each claimed limitation, **including the erodible polymers and the size of the caplets,** Applicants respectfully submit that the Examiner has failed to prove a *prima facie* case of obviousness, which requires that the prior art references teach or suggest all of the claimed limitations. It is clear that the prior art reference cited by the Examiner fail to accomplish this and there is no motivation to modify the reference, and thus the claims are not obvious over the references. Applicant, therefore, respectfully request reconsideration and withdrawal of the alternative obviousness rejection.

Accordingly, Applicant respectfully submits that the present inventive subject matter, as claimed in the rejected claims, is not rendered obvious by the Krishnamurthy patent. Applicant request reconsideration and withdrawal of these rejections.

**CONCLUSION**

In view of the foregoing, Applicant respectfully submits that the present claims are patentable over the prior art of record in this case and requests the Examiner to reconsider and withdraw the rejection of the claims and to allow all of the claims pending in this application.

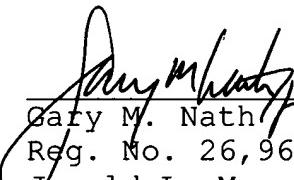
If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

Respectfully submitted,

**NATH & ASSOCIATES**

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